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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,147	03/30/2007	Gurmit Singh-Gill	AJPARK38.001APC	9247

20995 7590 08/06/2009  
KNOBBE MARTENS OLSON & BEAR LLP  
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EXAMINER
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BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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08/06/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,147	<b>Applicant(s)</b> SINGH-GILL ET AL.	
	<b>Examiner</b> LAYLA BLAND	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-9,11-13, 20-28, 30 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 7-9, 11, 12, 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/7/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This application is a national stage entry of International Application No. PCT/NZ04/00293, filed November 18, 2004, which claims priority to New Zealand Applications No. 533245, filed on May 31, 2004 and 529603, filed on November 18, 2003. The certified copies of the priority documents have been filed with the instant Application.

Applicant's amendment of claim 1 and election with traverse of Group I, claims 1, 2, 4, 5, 7-9, 11, 12, and 30 in the reply filed on June 23, 2009 is acknowledged. The traversal is on the ground(s) that Applicant has removed the species taught by Wan by proviso, and that the inventions relate to a single general inventive concept. This is not found persuasive because compounds encompassed by claim 1 are known in the art, as will be set forth below, and thus the inventions do not share a special technical feature. Applicant also traverses on the ground that group B is comprised of polar heteroatom linking groups, which is a single inventive concept. This argument is not persuasive because the linkers recited in B comprise different functional groups and result in compounds having different core structures, and thus they do not make up a single inventive concept.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 4, 5, 7-9, 11-13, 20-28, and 30 are pending.

Claims 13 and 20-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

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generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 23, 2009.

Claims 1, 2, 4, 5, 7-9, 11, 12, and 30 are examined on the merits herein.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 7-9, 11, 12, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and dependent claims 2, 4, 5, 7-10, 11, and 12, the definition of E includes  $-\text{CHR}_3-\text{CHR}_4-$ , wherein  $\text{R}_3$  and  $\text{R}_4$  can be  $\text{CH}_2-$  or  $\text{CH}((\text{CHOH})_m\text{CH}_2\text{OH})-$ . It is presumed that the dashes represent points of connectivity to B and D. Because  $\text{CH}_2-$  or  $\text{CH}((\text{CHOH})_m\text{CH}_2\text{OH})-$  also include dashes, it is unclear whether linker groups containing these moieties are intended to be linear (like the last structure in claim 30) or branched (like the first structure in claim 30).

Claim 1 and dependent claims 2, 4, 5, 7-10, 11, and 12 recite that D can comprise two or more separate sugar moieties attached to E at different sites. It is unclear how many separate sugar moieties may be present, and at which positions they are attached to E. It is unclear whether attachment of sugar moieties to the  $-\text{OH}$  groups present in E is intended.

Claim 1 and dependent claims 2, 4, 5, 7-10, 11, and 12 recite the limitation “D comprises at least one sugar moiety.” Because “comprising” is open language, it is unclear which other moieties may be present as part of D, essentially leaving the claim open-ended.

Claims 8 and 9 are drawn to the molecule of claim 1, wherein D comprises a monosaccharide or oligosaccharide chain. It is unclear whether the claims require a monosaccharide chain or oligosaccharide chain, or if the claims require either a monosaccharide or an oligosaccharide. Put another way, it is unclear whether a compound wherein D is a monosaccharide is encompassed by claims 8 and 9. If the first interpretation, a monosaccharide chain or oligosaccharide chain, is intended, the difference between a monosaccharide chain and an oligosaccharide chain is unclear.

Claim 11 depends from claim 1 and recites the limitation “E is  $-\text{CHR}_3\text{CHR}_4-$ , wherein  $\text{R}_3$  is  $\text{CH}_2-$  and  $\text{R}_4$  is H.” Claim 1 includes the proviso “when  $\text{R}_3$  is H or  $\text{CH}_2$  that  $\text{R}_4$  is not H or  $\text{CH}_2$ .” These are contradictory definitions. Thus, it is impossible to determine which structure is intended in claim 11.

Claim 30 depends from claim 1 and recites structures wherein one of  $\text{R}_3$  is H and the other is  $\text{CH}_2$  (the first, third, fourth, and fifth structures), which is explicitly prohibited by claim 1. The last structure in claim 30 contains a moiety A which is not encompassed by the definition of A in claim 1, because it is not a glyceride or a linear or branched alkyl. Thus, it is impossible to determine which structures were intended in claim 30.

**Claim Rejections - 35 USC § 102**

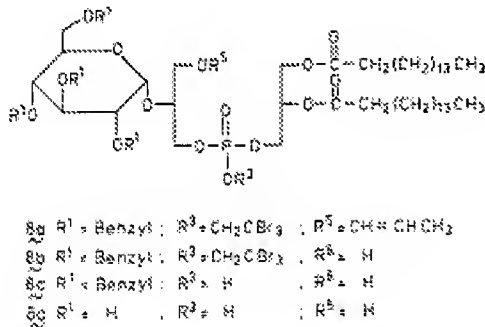
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by van Boeckel et al. (Tetrahedron Letters No. 37, pp 3561-3564, 1979, PTO-1449 submitted June 7, 2007).

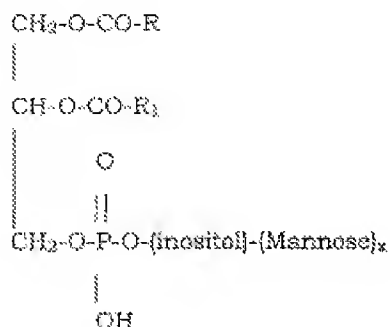
Van Boeckel teaches glucosyl phosphatidylglycerol 8d, shown below [page 3536]:



In this case, A is (1a) wherein  $R_1$  and  $R_2$  are palmitate; B is phosphate; E is  $-\text{CHR}_3-\text{CHR}_4-$  wherein one of  $R_3$  and  $R_4$  is H and the other is  $\text{CH}_2\text{OH}$ ; and D is glucose. The proviso “when  $R_3$  is H,  $R_4$  cannot be  $\text{CH}_2\text{OH}$ ” is noted. However, the above compound can be considered one wherein  $R_3$  is  $\text{CH}_2\text{OH}$  and  $R_4$  is H, because no particular connectivity is required for the linker group. Thus, the claims are anticipated.

Claims 1, 2, 4, 5, 7-9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Severn et al. (WO 02/02410, January 10, 2002).

Severn teaches the following compounds [page 9]



wherein X is 1 to 40, preferably 1 to 6, and R and R<sub>1</sub> independently represent a fatty acid chain.

Preferably, the fatty acid units are 16-20 carbon atoms in length, such as myristate, palmitate, etc. [page 9, lines 10-14]. In this case, A is (Ia) wherein R<sub>1</sub> and R<sub>2</sub> are acyl of 16-20 carbons; B is phosphate; E is inositol (cyclohexyl substituted with hydroxyl groups); and D is mannose or a mannose oligosaccharide of preferably 1-6 units. The compounds are formulated for respiratory, subcutaneous, intradermal, intramuscular, etc. administration to a patient [page 5, lines 15-24] and may be administered with an adjuvant [page 7, lines 13-15].

See MPEP 904.02: "During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification." Inositol is a cyclohexyl group substituted with hydroxyl groups. The instant specification, page 9, states that the linking group E may be substituted with hydroxyl groups or functionalities

which allow the attachment of one or more sugar chains. Thus, it is considered that inositol meets the limitation -cyclohexyl- in claim 1, and the claims are anticipated.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 7-9, and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/311,340. Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn to molecules of formula I where E can be cyclohexyl or substituted cyclohexyl. As was set forth above, the broadest reasonable interpretation of “cyclohexyl” in instant claim 1 includes inositol.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/  
Examiner, Art Unit 1623

/Shaojia Anna Jiang/  
Supervisory Patent Examiner  
Art Unit 1623

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